



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/662,570

09/15/2003

Jonathan S. Stinson

81636D

9734

23685 7590 12/07/2006

KRIEGSMAN & KRIEGSMAN
30 TURNPIKE ROAD, SUITE 9
SOUTHBOROUGH, MA 01772

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,570

Applicant(s)

STINSON ET AL.

Examiner

Elizabeth Houston

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) 35-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 091503, 010504
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 09/15/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Election/Restrictions

1. Applicant's election without traverse of species of Figures 4 and 5, claims 24-34 in the reply filed on 10/02/06 is acknowledged.
2. Claims 35-46 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/02/06.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 3731

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 24-28, 30, 31 and 33 rejected under 35 U.S.C. 102(e) as being anticipated by Gambale et al (USPN 6,458,092).

5. Gambale discloses a stent delivery system comprising: an inner catheter (80) with a first lumen; perforating means (82,84) slidably disposed in the first lumen; an outer catheter (36) adapted for axial movement relative to the inner catheter; a self expandable stent (70) disposed between the inner and outer catheter. The stent is coaxially mounted over the inner catheter (90). The stent can be a braided filament (Fig. 5a, b) or non-absorbable plastic (Col 12, line 64). The stent has uniform diameter (Fig. 1B) and is shaped to include a waist of lesser-expanded diameter and a pair of cuffs on opposite ends (Fig. 1D). The perforating means is a retractable needle.

6. Claims 24, 25, 29-31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Phelps et al (USPN 6,290,728).

7. Phelps discloses a stent delivery system comprising: an inner catheter (22) with a first lumen; perforating means (16) slidably disposed in the first lumen; an outer catheter (26) adapted for axial movement relative to the inner catheter; a self expandable stent (20) disposed between the inner and outer catheter. The stent is coaxially mounted over the inner catheter. The stent is made of bio-absorbable material (Col 7, line 33). One embodiment of a stent has uniform diameter (Fig. 12) and another

Art Unit: 3731

is shaped to include a waist of lesser-expanded diameter and a pair of cuffs on opposite ends (Fig. 4). The perforating means is a retractable needle.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24, 25, 27, 30, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson (USPN 6,599,315) in view of Haarstad et al (USPN 6,533,753) and further in view of Phelps et al. (USPN 6,290,728).

10. Wilson discloses a stent delivery system comprising: an inner catheter (120) with a first lumen (125) with a guide wire (150) slidable disposed in the first lumen; a second lumen (126) with a guidewire (151) slidably disposed in the second lumen; and a self expandable stent (20) (Col 6, line 62) coaxially disposed over the inner catheter. The stent is made of non-absorbable material (Col 6, lines 38-42). The stent has uniform diameter.

11. Wilson does not disclose that the first guidewire is a perforating means that is a retractable needle.

12. Haarstad discloses that it is well known in the art to use a stiff guidewire to penetrate lesions referred to as "chronic total occlusions" (Col 1, lines 40-51). In this case the guidewire is considered the perforating means or needle.

Art Unit: 3731

13. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a stiff guidewire into the stent delivery device in order to more easily traverse a stenosis that may be fully occluding the vessel. It is well known in the art as evidenced by Haarstad.

14. Wilson in view of Haarstad does not disclose an outer catheter.

15. Phelps discloses that it is well known to use a sheath (outer catheter) to restrain a self-expanding stent to hold the stent in a non-expanded configuration.

16. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a sheath into the stent delivery device when it is used for a self-expanding stent. It is well known in the art to use a sheath to restrain self-expanding stents as evidenced by Phelps.

17. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phelps.

18. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale.

19. Phelps and Gambale disclose the invention substantially as claimed as stated above except for the disclosed dimensions of the diameter and the length of the stent. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the dimensions of the diameter and length of the stent depending on the size of the patient and the location where the stent is to be used. Additionally, such a modification would have involved a mere


Art Unit: 3731

change in the size of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh 


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

12/5/06.